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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER
KUBELIK, ANNE R

ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 07/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/901,737	LEBEL ET AL.	
	Examiner	Art Unit	
	Anne R. Kubelik	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 April 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *8,9,14,15,20-23 and 30-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8,9,14,15,20-23 and 30-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 27 April 2006 has been entered.

2. Claims 8-9, 14-15, 20-23 and 30-34 are pending.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. The objection to claims 8-9, 16-17, 19-21 and 23 because of an informality is withdrawn in light of Applicant's amendment of the claims.

5. The rejection of claims 8-9, 14-15 and 30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention is withdrawn in light of Applicant's amendment of the claims.

Claim Rejections - 35 USC § 112

6. Claims 8-9, 14, 20-23 and 30-34 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The rejection is repeated for the

reasons of record as set forth in the Office action mailed 22 November 2005, as applied to claims 6-9, 14, 16-17, 19-23 and 30. Applicant's arguments filed 27 April 2006 have been fully considered but they are not persuasive.

A full review of the specification indicates that nucleic acids encoding microbial β-1,4-endoglucanses are essential to the operation of the claimed invention

Thomas et al teaches that more than 60 species of fungi and 46 species of bacteria produce cellulases (pg 210, paragraph 2). The specification, via Thomas et al, Collmer et al, Ghangas et al, Wilson, and Lao et al, describes a total of about 20 coding sequences from about 12 bacterial species and one fungal species endoglucanase; which of these are β-1,3-endoglucanses and which are β-1,4-endoglucanses is not indicated.

Claims 14 and 31 are drawn a plant transformed with a β-1,4-endoglucanse from any *Thermomonospora* species; however, the specification describes only β-1,4-endoglucanses from one species, *T. fusca*. However, the *Thermomonospora* genus includes 6 other species, *T.alba, T. chromogena, T. curvata, T. formosensis, T. mesophila,* and *T. mesouviformis*; no nucleic acids encoding β-1,4-endoglucanses are described from any of these species.

Claims 21 and 32 require that the microbial β-1,4-endoglucanses be thermostable. The specification fails to describe the structural features that confer thermostability on a microbial β-1,4-endoglucanse.

The specification does not describe as relevant characteristics of microbial β-1,4-endoglucanses. Structural features that distinguish microbial β-1,4-endoglucanses from β-1,4-

endoglucanses from non-microbial sources, including synthetic, are not described in the specification.

One of skill in the art would not recognize that Applicant was in possession of the necessary common attributes or features of the genus in view of the disclosed species. Since the disclosure fails to describe the common attributes that identify members of the genus, and because the genus is highly variant, the disclosed species are insufficient to describe the claimed genus.

Hence, Applicant has not, in fact, described plants transformed with nucleic acids that encode microbial β-1,4-endoglucanses within the full scope of the claims, and the specification fails to provide an adequate written description of the claimed invention.

Therefore, given the lack of written description in the specification with regard to the structural and functional characteristics of the claimed compositions, it is not clear that Applicant was in possession of the claimed genus at the time this application was filed.

Applicant urges that the specification teaches 3 *T. fusca* endoglucanases and the cited references describe other cellulases from bacterial and fungal sources, citing Collmer, Ghanges, Wilson, Jung, Lao, and Thomas (response pg 5-6).

This is not found persuasive because Collmer, Ghanges, Jung and Lao only teach the *T. fusca* endoglucanase genes and Thomas only teaches enzymes, not sequences.

Applicant urges that Wilson teaches numerous genes on pg 46 and 56 (response pg 6).

This is not found persuasive because what is taught on pg 46 is enzymes and *T. fusca* genes. While genes from three bacteria other than *T. fusca* are referenced on pg 56, it is not clear

which of these encode β-1,4-endoglucanses - certainly several are identified as "exocellulases" which would not be endoglucanases - and which, if any, β-1,4-endoglucanses are thermostable is not indicated.

Applicant urges that Lao et al teaches *T. fusca* E2 and E5 and a portion of E4 (response pg 6).

This is not found persuasive because the instant specification teaches E1 and E5; E4 is incomplete, and thus not described.

Applicant urges that Thomas describes endoglucanases from fungi and bacteria on pg 209, and that more than 60 species of fungi and 46 species of bacteria produce endoglucanases (response pg 6).

This is not found persuasive because Thomas does not teach the sequences of any of the cellulases.

Applicant urges that GenBank teaches three fungal endoglucanases (response pg 6-7).

This is not found persuasive because these three endoglucanases sequences do not describe the other at least 57 fungal endoglucanase sequences.

See *Univ. of California v. Eli Lilly*, 119 F.3d 1559, 43 USPQ 2d 1398 (Fed. Cir. 1997) at pg 1406:

> ... the claimed genera of vertebrate and mammal cDNA are not described by the general language of the '525 patent's written description supported only by the specific nucleotide sequence of rat insulin.

7. Claims 8-9, 14, 20-23 and 30-34 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for plants transformed with *T. fusca* β-1,4-endoglucanse-

encoding sequences, does not reasonably provide enablement for plants transformed with nucleic acids encoding any microbial β-1,4-endoglucanse. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. The rejection is repeated for the reasons of record as set forth in the Office action mailed 22 November 2005, as applied to claims6-9, 14, 16-17, 19-23 and 30. Applicant's arguments filed 27 April 2006 have been fully considered but they are not persuasive.

The claims are broadly drawn to plants transformed with a nucleic acid encoding any cellulase from any source.

In contrast, the instant specification, however, only provides guidance for expression of constructs comprising a nucleic acid encoding the *T. fusca* E1, E2 or E5 β-1.4-endoglucanse operably linked to the tobacco PR-1a or the CaMV 35S promoter in tobacco, maize or wheat (example A) and similar expression in plants of constructs encoding fusion proteins of those endoglucanases and a vacuolar signal sequence (example B). The specification, via Thomas et al, Collmer et al, Ghangas et al, Wilson, and Lao et al, teaches a total of about 20 endoglucanase (presumably β-1,4-endoglucanse) coding sequences from about 12 bacterial species and one fungal species, 2 cellobiohydrolase coding sequences, one from a bacterial species and one from a fungal species, and 2 β-glucosidase coding sequences, one from a bacterial species and one from a fungal species.

The instant specification fails to provide guidance for a representative number of other nucleic acids encoding cellulases, and hence for all plants comprising said nucleic acids.

Claim 14 is drawn a plant transformed with a cellulase from any *Thermomonospora* species; however, the specification teaches only β-1,4-endoglucanses from one species, *T. fusca*. However, the *Thermomonospora* genus includes 6 other species, *T.alba, T. chromogena, T. curvata, T. formosensis, T. mesophila,* and *T. mesouviformis*; no nucleic acids encoding cellulases are taught from any of these species.

The specification does not teach how to make microbial β-1,4-endoglucanses other than those taught in Thomas et al, Collmer et al, Ghangas et al, Wilson, and Lao et al, and does not teach how to distinguish microbial β-1,4-endoglucanses from β-1,4-endoglucanses from other sources, including synthetic.

The specification only teaches one source of thermostable microbial β-1,4-endoglucanses, those from *T. fusca*, and does not teach how to make other thermostable microbial β-1,4-endoglucanses.

Given the claim breath and lack of guidance in the specification as discussed above, the instant invention is not enabled throughout the full scope of the claims.

Applicant urges that enablement doesn't require detailed description of every possible embodiment (response pg 8).

This is not found persuasive because the specification must provide guidance within the full scope of the claims; it does not.

Applicant urges that the claimed method call for integration into plant cells a construct encoding a β-1,4-endoglucanse; the critical aspect of the method is not the nature of the

endoglucanase, but rather the use of appropriate regulatory sequences that function in plant cells (response pg 8-9).

This is not found persuasive. The claimed method call for integration into plant cells a construct encoding a microbial β-1,4-endoglucanse. The nature of the β-1,4-endoglucanse is critical.

Applicant urges that in the advistory action the Office admitted plant promoers are described within the full scope of the claims (response pg).

This is not found persuasive. Both the nucleic acids encoding the microbial β-1,4-endoglucanases and the promoters must be taught for the invention to be taught. Nucleic acids encoding B-1,4-endoglucanases from bacteria and fungi and not described within the full scope of the claims.

Applicant urges that it does not serve the purpose of patents if others may take Applicajnt's example and substitute endoglucanases from sources other than T. fusca; substituting one endoglucanase fro another is not undue experimentation (response pg).

This is not found persuasive. It is undue experimentation if microbial β-1,4-endoglucanse are not known within the full scope of the claims. Furthermore, the ability of the public to successfully design around - to use the patent disclosure to design a product or process that does not infringe, but like the claimed invention, is an improvement over the prior art - is one of the important public benefits that justify awarding the patent owner exclusive rights to his inventions (*ATD Corp. v. Lydall Inc.* 43 USPQ2d 1170 (DC EMich 1997), 1178).

Claim Rejections - 35 USC § 103

8. Claims 8, 14-15 and 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Van Ooyen et al (US Patent 5,705,375, filed June 1992) in view of Lao et al (1991, J. Bacteriol. 173:3397-3407). The rejection is repeated for the reasons of record as set forth in the Office action mailed 22 November 2005, as applied to claims 6-8, 14-17, 19, 21-23 and 30. Applicant's arguments filed 27 April 2006 have been fully considered but they are not persuasive.

The claims are drawn to plants transformed with a nucleic acid encoding microbial endoglucanase, including those that are transformed with a nucleic acid encoding a microbial endo-β-1,4-glucanase.

Van Ooyen et al disclose plants and seeds transformed with the *Bacillus licheniformis* α-amylase coding sequence under control of a constitutive (35S) promoter or an inducible (patatin) promoter (column 11, lines 45, to column 14, line 57). Van Ooyen et al do not disclose plants transformed with a nucleic acid encoding microbial endoglucanse.

Lao et al teach nucleic acids encoding the *T. fusca* E2 and E5 β-1,4-endoglucanases, which are thermostable.

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to modify the method of expressing microbial genes in plants as taught by Van Ooyen et al, to the nucleic acids encoding β-1,4-endoglucanases from *T. fusca* described in Lao et al. One of ordinary skill in the art would have been motivated to do so because of the suggestion of Van Ooyen et al to express microbial β-1,4-endoglucanases in plants (column 4, lines 11-36)

9. Claim 9 is free of the prior art given the failure of the prior art to teach or suggest plants transformed with a construct comprising a microbial β-1,4-endoglucanase coding sequence operably linked to a PR-1, PR-1a, PR-2, PR-3, PR-4, or PR-5 promoter. Claims 20 and 31-34 are free of the prior art given the failure of the prior art to teach or suggest plants transformed with a construct comprising nucleic acid encoding a microbial β-1,4-endoglucanase coding sequence operably linked to vacuole-targeting sequence.

Conclusion

10. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (571) 272-0801. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg, can be reached at (571) 272-0975.

The central fax number for official correspondence is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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Anne Kubelik, Ph.D.
June 26, 2006